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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,001	12/13/2006	Matthias Augustin	P30391	1364
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EXAMINER DAVIS, DEBORAH A				
ART UNIT		PAPER NUMBER		
1655				
NOTIFICATION DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/588,001

Applicant(s)

AUGUSTIN ET AL

Examiner

DEBORAH DAVIS

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48-71 is/are pending in the application.
- 4a) Of the above claim(s) 50-53, 55-59, 63 and 64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48-49, 54, 60-61, and 65-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicants' amendment filed January 28, 2011 has been received and entered. Currently, claims 48-71 are pending. Claims 48-49, 54, 60-61 and 65-71 are under consideration for examination. Claims 50-53, 55-59, and 62-64 are withdrawn from consideration as not reading on the elected species.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 48-49, 54, 60-62, and 65-71 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating a microbe-caused disease of at least one skin condition disclosed in the instant claims, does not reasonably provide enablement for preventing a microbe-caused disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors regarding undue experimentation have been summarized in *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Circ. 1988) as follows:

- (1) The quantity of experimentation necessary (time and expense);
- (2) The amount of direction or guidance presented;

- (3) The presence or absence of working examples of the invention;
- (4) The nature of the invention;
- (5) The State of the prior art;
- (6) The predictability or unpredictability of the art;
- (7) The breadth of the claims; and
- (8) The relative skill of those in the art

All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the invention: The instantly claimed invention is drawn to a method of treating or preventing a microbe-caused disease of at least one of skin, a mucous membrane and an oral cavity, wherein the method comprises an administration to a subject of an amount of oil of coriander which is effective for treating or preventing the microbe-caused disease

Breadth of the claims: The claims were given its broadest and reasonable interpretation that is consistent with applicant's specification.

Guidance of the Specification and Existence of Working Examples:

The specification describes a clinical screening study of coriander oil in healing and treating experiments in which it demonstrated efficacy against atypical eczema and nummular eczema. The coriander oil treatment also proved to be effective against tinea diseases as well as Candida interigo. However, the specification does not show any working examples of where the coriander oil prevented any of the microbe-caused diseases of the mucous membrane, oral cavity or the skin. Although the M.P.E.P. does

not require working examples, there must be sufficient teaching in the specification to enable one of ordinary skill in the art to use the method as instantly claimed. The specification lacks such teaching and therefore the subject matter for "preventing" such microbe-caused diseases is not enabled. Thus, there has not been provided adequate guidance in the specification for accomplishing this process using the oil of coriander as claimed.

Amount of Experimentation Necessary:

The quantity of experimentation necessary to carry out the claimed invention is high, because the skilled artisan could not rely on the instant specification or the prior art to teach a method of administering the oil of coriander to *prevent* a microbe-caused disease. Therefore, in view of the nature of the invention, breadth of the claims and the lack of guidance in the specification as well as the amount of experimentation necessary, the skilled artisan would not be able to practice the invention. Therefore the instant claims are not considered to be fully enabled by the instant specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 48-49, 54, 61-62, 65-69, and 71 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Lilley et al UK Publication (GB 2 359 746) for reasons of record and restated below:

A method of treating a microbe-caused disease of at least one of skin, a mucous membrane and an oral cavity, wherein the method comprises an administration to a subject of an amount of oil of coriander which is effective for treating the microbe-caused disease is apparently claimed.

The cited reference of Lilley et al. beneficially teaches the instant claims by disclosing a one or more of essential oils selected from coriander and others therein for the inhibition of pathogenic bacteria in the oral cavity that define such disorders as gingivitis, periodontal disease, dental caries and particularly disorders related to or caused by the activity of anaerobic bacteria (gram positive bacteria), which the examiner interprets of microbe-caused diseases, as claimed (page 3, lines 5-30, e.g.). The oral cavity comprise of skin, teeth and gum. Therefore the oral cavity read on skin. The coriander oil can be suitable for administration to humans and animals in the form of chewing gum, dental floss, mouth rinses (i.e. solution), toothpaste and other dental vehicles (page 11, lines 13-15, e.g.), which would be the contact site for the skin oral cavity. Such oral preparations are applied by contacting the gums by rinsing the oral cavity for about 15-90 seconds, or in the case where lozenges, candy or chewing gum are used by sucking or chewing in the oral cavity at least once daily (page 26-31, e.g.). This all includes topical treatment of the oral cavity. There coriander oil and be in

combination with other oils such as peppermint, lemongrass and others therein which have an antibacterial effect (see page 3, lines 19-23, e.g.).

The reference of Lilley et al. does not expressly teach the active step of administering coriander oil to a mammal.

However, the reference of Lilley does teach that the composition is in administrable forms and is useful for topical treatment of the oral cavity which includes the skin. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to administer coriander oil to a mammal based on the beneficial teachings provided by the reference of Lilley. The coriander oil comes in administrable forms for delivery to the oral cavity to treat gingivitis, periodontal disease, and other dental disorders. The adjustment of particular conventional working conditions (i.e. determining suitable concentrations coriander oil) is deemed merely a matter of judicious selection and routine optimization, which is well within the purview of the skilled artisan.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of the evidence to the contrary.

Claims 60 and 70 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Lilley et al as applied to claims 48-49, 54, 61-62, 65-69, and 71 above, and further

in view of Gail B. Mahady (Thai Journal of Phytopharmacy Vol. 9(1) June. 2002, pages 50-62) for reasons of record and restated below:

The teachings of Lilley have been set forth above but do not expressly teach the that the microbe-caused disease is associated with at least one of Methicillin-resistant *Staphylococcus aureus* and a multi-resistant pathogen.

However, the reference of Mahady beneficially teaches that the overuse of antibiotics has been linked to drug resistance in some pathogens such as methicillin-resistant *Staphylococcus aureus* and *Mycobacterium tuberculosis* in man. Mahady beneficially teaches that many essential oils of medicinal plants have antimicrobial activity against such pathogens. Essential oils from coriander and others disclosed therein were tested for their ability to inhibit bacterial growth in the pathogens such as *Staphylococcus aureus*, *Escherichia coli*, *Listeria monocytogenes*, *Aspergillus niger*, *Pseudomonas aeruginosa* and others therein listed (See pages 52, col. 1, Table 1, page 59, col. 1, and Table 2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to consider the use of coriander oil to treat multi-resistant pathogens with the composition of Lilley because Mahady teaches that such pathogens can become multi-resistant to the over use of antibiotics and therefore need an alternative treatments as in essential oils that include coriander.

Response to Arguments

Claim Rejections - 35 USC § 112 arguments:

Applicant traverses this rejection based on the assertion that the specification's definition of prophylaxis treatment is always mentioned with the term treatment. Applicant argues that it is well known that preventive/prophylactic therapy of a disease is carried out by administering the same agent by the same route of administration in the same amounts against the same disease with the expectation that the disease will not appear. Applicant argues that there are several examples in the instant specification of preventing microbe caused disease using coriander oil. Applicant argues that a clear example is the treatment of embolism which is affected by the same route of administration in the same amounts of the same agent as a treatment of chronic embolism. These arguments has been carefully considered but not found to be persuasive of error.

In response, if applicant is claiming the prophylaxis treatment of specific microbe-caused disease then these limitations should be put into the claims and provide support in the specification. With respect the embolism, this is a condition and not a disease. As applicant has acknowledged, embolism can be treated with blood thinners (heparin) and other treatments to prevent blockage of an artery. As it stands, applicant's claims as drafted read on preventing disease; specifically every microbe caused disease. Applicant does not have support for preventing any and all microbe-caused diseases. Neither does the prior art teaches or suggest that the oil of coriander when administered can **prevent** microbe-caused disease.

Therefore, this rejection is hereby maintained and made final.

Claim Rejections - 35 USC § 103 rejection:

Applicant traverses the rejection of record for all of the arguments set forth in the previous Office Action, which applicant incorporates herein. Applicant argues that the passage of Lilley (i.e. page 3, lines 14-23) conveys a strong impression that the oils disclosed in Lilley exhibit significant activity only against bacteria which is strongly implicated in periodontal disease and/or malodour. Applicant argues that this is a disincentive rather than a motivation for one skilled in the art to use the oil of coriander for the treatment or prevention of a disease which is not strongly implicated in periodontal disease and/or malodour. These arguments have been carefully considered but not found to be persuasive of error.

In response, the examiner directs applicant's attention to the teaching of Lilley that discloses:

It has now been found that certain essential oils, which in earlier studies had previously demonstrated only weak antibacterial activity, are particularly potent in their antibacterial effect against species of bacteria which are strongly implicated in periodontal disease and/or malodour production. According to the present invention there is provided the use of an effective amount of one or more essential oils selected from coriander oil, cummin oil, dill weed oil, lemongrass oil and peppermint oil in the manufacture of a composition for the inhibition of pathogenic bacteria, particularly anaerobic bacteria, present in the oral cavity of humans and other mammals, the composition being suitable for oral administration.

Thus, the above teaching clearly implicates that coriander and other essential oils disclosed therein are useful for treating microbe caused diseases, even if the disease is periodontal. It is also clear that periodontal disease is caused by bacteria.

In response to applicant's argument that the oral cavity is not skin is not persuasive. The examiner still maintains that the oral cavity is made of skin, teeth and bone. The oral cavity has an epithelial covering and thus read on skin. Applicant is invited to see a standard dictionary meaning for epithelial.

Applicant argues that the reference of Lilley only discloses the administration of combinations of essential oils to the oral mucosa of patients. Applicant argues that there is no working example supporting the administration of a single essential oil of coriander. These arguments have been carefully considered but not found to be persuasive of error.

In response, the M.P.E.P. does not require working examples but does require a sufficient teaching of the subject matter. Further, the claims recite the open language of "comprising" and therefore do not prohibit other essential oils and ingredients from being disclosed therein.

Applicant argues that there is no motivation to combine the reference of Mahady with Lilley. Applicant argues that one of ordinary skill in the art would not assume that the species of bacteria implicated in periodontal disease and/or malodour, taught by Lilley would be concerned with Methicillin-resistant *Staphylococcus aureus* and/or multi-resistant pathogens and neither has the examiner. These arguments have been carefully considered but not found to be persuasive of error.

In response, the motivation to combine the reference of Mahady with Lilley comes from the teachings of Mahady. Mahady teaches that the overuse of antibiotics is linked to drug resistance pathogens such as Methicillin resistant *Staphylococcus aureus*. Therefore essential oils were tested to remedy this problem. It was discovered that essential oils that include coriander have the ability to inhibit bacterial growth in such pathogens as *Staphylococcus aureus*, *E. coli*. The claims require a method of treating microbe related diseases that include Methicillin resistant *Staphylococcus* with coriander oil and therefore the teaching of Lilley in view of Mahady clearly makes obvious the claimed subject matter with a clear motivation provided.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEBORAH DAVIS whose telephone number is (571)272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Deborah A. Davis
Patent Examiner, AU 1655
April 2011

/Christopher R Tate/
Primary Examiner, Art Unit 1655